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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,575	03/31/2004	Ilya Malyarov	2008P26174 US	4329

28524 7590 08/07/2009

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ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/813,575
Filing Date: March 31, 2004
Appellant(s): MALYAROV ET AL.

Vincent M. DeLuca
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 26, 2009 appealing from the Office action mailed September 10, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-4 and 10-17.

Claims 5-9 are now objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 is withdrawn from consideration as not directed to the elected invention.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on December 10, 2008 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) *requires* the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims

involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

The brief is deficient because it does not contain a concise explanation of the subject matter defined in independent claim 1 involved in the appeal referring to the Figures 2-5D by reference characters.

The Office hereby provides a corrected summary of the claimed subject matter defined in claim 1 referring to the Figures and reference characters.

Claim 1. An analyte detection station for an automated immunoassay analyzer, comprising:

a read station (2 in Figs. 2 and 3) rotatable between an entry position (9 in Fig. 3) and a read position (10 in Fig. 3);

a detector (4 in Fig. 2) coupled to the read station (2) at the read position (10) for detecting radiant energy or color emanating from the read station;

a wash station (6 in Fig. 2) that performs a wash operation;

a transport device (i.e., luminometer belt 3 in Fig. 2) that receives vessels from the wash station (6) and for transporting a plurality of vessels from the wash station (6) through a defined path (not shown but disclosed as the belt 3 rotating in a clockwise or

counterclockwise direction; see page 7, lines 7-9), each of the vessels containing at least one bound analyte and at least one compound for emitting radiant energy or color, and for transferring one of the plurality of vessels from the defined path into the read station at the entry position (9);

wherein the read station (2) is capable of rotating a transferred vessel from the entry position (9) to the read position (10) independently of motion of the plurality of vessels through the defined path (not shown).

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: claims 1-4 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson et al., (US Patent No. 5,885,529)

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the Examiner. Appellant's newly presented arguments to claim 5, in which Appellant argues that the read station (i.e., chain 215a) of Babson does not include a shield is deemed persuasive. Claims 6-9 are objected to because they directly, or indirectly, depend from claim 5.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,885,529	BABSON et al.	03-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson et al. (US Patent no. 5,885,529), hereinafter "Babson".

Babson teaches an analyte detection station for an automated immunoassay analyzer, comprising:

a reaction reading station (i.e., an oval luminometer chain 215a) that rotates between an entry position (near the wash station 214) and a read position (i.e., in front of a detector 216a), see col. 8, line 31; Figs. 2a, 2b;

a detector (photomultiplier tube 216a) is coupled with the read station for detecting radiant energy from emanating from the read station;

a wash station 214 that performs a wash operation (see for example col. 8, lines 6-10); and

a transport device (i.e., side chain 213b) for transporting a plurality of vessels through a defined path. The transport device 213b rotates between wash station 214 (near the entry position of the read station) and a pipette station 204. The wash station 214 includes an angled, splined chuck surrounded by a receptacle and a tube elevating device (as shown in FIGS. 8A and 8E). Reaction tubes are elevated onto this

chuck and then rotated about their longitudinal (vertical) axes at high speed. Thus, the tubes are removed from transport device 213b of Babson into the wash station 214 to be washed. After washing the beads at the wash station 214, the reaction tubes are lowered by the chuck. The transport device 213b receives the vessels from the wash station and transports the reaction tubes to reaction pipetting station 204 along a path defined by the side chain 213b where more reagent(s) is added, if necessary (see col. 7, line 66 - col. 8, line 39). After reagent addition, the transport device (chain 213b) transfers the reaction vessels from the defined path (defined by chain 213b) to the wash station where the step of incubation and wash are repeated (see col. 8, lines 21-29) and then into the read station (i.e., 215a) at its entry position.

Note the open "comprising" language of the claims does not preclude the transport device 213b from transferring the plurality of vessels from the defined path of the transport device and into the read station 215a via the wash station 214.

Further note, that the read station 215a of Babson is capable of rotating a transferred vessel from its entry position to the read position *independently* of the motion of the plurality of vessels through the defined path of the transport device 213b.

Regarding claims 2 thru 4, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., chemiluminescence, fluorescence, phosphorescence, etc.,) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches *all the structural limitations* of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). While Babson does not explicit teach a detector that detects phosphorescence, such a limitation is merely an intended use, which the prior art would

inherently be capable of doing. The only distinction between Appellants' claims and the prior art is recited functional language. It is incumbent upon Appellants to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re* Ludtke, 169 USOQ 563 (CCPA 1971). Moreover, Babson explicitly teaches fluorescent, radioactive, and chemiluminescent detection (see col. 1, lines 20-34 and col. 8, lines 40-64).

Regarding claims 10 and 11, the transport device of Babson is a continuous belt having teeth (i.e., receptacle vessels) that receive the plurality of vessels. The belt can receive the vessel at a plurality of locations.

With respect to claims 12-16, Babson's analyzer system includes an attenuation means (rotatable filter wheel) for attenuating light signals. The attenuation means is located between the read station 215a and the detector 216a, and can be set at any three attenuation positions (see col. 9, lines 21-49). The three attenuation positions include: an unattenuated position where light from the vessel can be read directly by the detector; an attenuated position where light from the vessel can be read by the detector through neutral density filter; and a dark position where no light from the vessel can be read by the detector.

Regarding claim 17, the detection station of Babson include a means for measuring dark counts (i.e., computer 12). The computer uses these values to calibrate "noise" in the PMT (col. 9, lines 44-49.)

(10) Response to Argument

In response to the rejection of independent claim 1 under 35 U.S.C. 102(b) as being anticipated by Babson, Appellant argues that as explained in the specification,

automated immunoassay analyzers such as those disclosed by Babson have traditionally performed testing of samples in a serial manner. That is, a sample is presented to the analyzer and it progresses step by step through the various processes until completion. While this first sample is progressing through the analyzer, all other samples follow. That is, there is a single path through currently available analyzers. Once the sample reaches the luminometer subsystem, it is then read using a detection mechanism while on the transportation element. This means the readings must be performed in a serial fashion on a first come first serve basis.

The Examiner respectfully disagrees. Babson specifically teaches an analyte detection station that, like the present invention, permits performing analyte detection in a randomized fashion, as opposed to a serial, one after the other, fashion. This allows for varying the time period between adding chemical reagents to the test vessel that interact with bound analyte to produce radiant energy or color change, and the time when the individual vessels are presented to the detector for analysis. In this way, the time duration for the type of test being performed can be optimized. Appellant's specification states in the Summary of the invention section this is accomplished by having *the transport section separate from the detector section, whereby transfer from the transport section to the detector section occurs under the direction of a controller* which effects the transfer at an interval that is preferably optimized for the test being performed, as well as in light of the other tests which are currently on the transport device. Babson specifically teaches as an object of the invention to provide an automated design which allows reduced user interface including the ability to order, perform and reassay tests reflexively based on test results without operator intervention.

In addition the computer controls *the timing of the incubation, mixing, washing and detection operations* (see Summary of invention section in Babson). Like the present invention, the analyte detection is Babson is in a *randomized* fashion, not a serial fashion. This is accomplished by having in Babson a transport section 213b which is separate or independent from the rotatable read station (215a).

Contrary to Appellant's assertion, the luminometer chain 215a does not simply pick up vessels from wash station 214 and transport them to reading station 216, where photometric reading of the reagent in the vessels is read by photomultiplier tube 216a, one at a time in a serial fashion, after which the vessel and its contents are moved by the chain 215a to waste. Rather, the Examiner asserts the analyzer of Babson includes a transport device 213b (continuous side chain) for transporting a plurality of vessels through a defined path. That is, the transport device 213b rotates between the wash station 214 (near the entry position of the read station) and a pipette station 204. Babson teaches when washing is required, the reaction tubes are elevated onto this chuck (i.e., removed from transport device 213b) and washed. After washing, the reaction tubes are lowered by the chuck back onto the transport device 213b, i.e., received from the wash station. The transport device 213b can then return the tube to reaction pipetting station 204 by rotation of the chain (see col. 7, line 66 - col. 8, line 39). After reagent addition, the transport device 213b transfers the reaction tubes from the path 213b to the wash station where the step of incubation and wash are repeated (see col. 8, lines 21-29) and shuttled out of the wash station 214 into the read station (i.e., 215a) at the entry position. See col. 8, lines 21-29. In other words, the

transport device 213b Babson transfers the plurality of vessels from the defined path of the transport device 213b and into the read station *via the wash station* 214.

Appellant argues that Babson fails to disclose a read station rotatable between an entry position and a read position, as recited in claim 1. Appellant argues the read station of 216 of Babson is stationary and does not rotate at all. Further, Appellant argues the rotating luminometer chain 215a of Babson cannot be interpreted as the claimed read station since Babson calls element 216 the "reading station", and this would allegedly be inconsistent with Babson disclosure itself and therefore outside the broadest reasonable interpretation of the claim.

The Examiner respectfully disagrees. Claim 1 defines the read station *solely* in functional language (i.e., rotatable between the entry position and a read position). The Examiner maintains that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus *must be* distinguished from the prior art in terms of structure rather than function. See MPEP 2114. There is *no structure* currently claimed that distinguishes the "read station" in claim 1 from the oval luminometer chain 215a of Babson. Thus, giving the claims the broadest reasonable interpretation, like the claimed read station, the luminometer chain 215a of Babson rotates between an entry position (at the wash station 214) and a read position at a detector (photomultiplier tube 216a), see col. 8, line 31; Figs. 2a, 2b of Babson. Further, the fact that Babson refers to element 216 as a "read station" is merely nominal and not germane to the issue. The Examiner asserts the reading station 216 in Babson acts as the housing which contains the, detector, luminometer shutter, and attenuator wheel (see col. 9, line 20-25).

Appellant also argues that the claims requires a transport device for transferring one of the plurality of vessels into the read station at the entry position thereof. The chain 213b does not allegedly transport vessels into the read station 216 (and neither does it transport vessels "into" the chain 215a), but instead transports vessels from the end back to the beginning of serpentine channel 213' (see col. 8, 11.4-6). Appellant argues Babson further discloses that if a vessel needs to be moved to wash station 214, it is shuttled out of tube processor 213 and picked up by a separate "circular chain" to be moved to wash station 214 (see col. 8, lines 6-10). Thus, chain 213b does not transfer vessels into a read station as required by the claims.

The Examiner respectfully disagrees with Appellant's argument. The analyzer of Babson includes a transport device 213b (continuous side chain) for transporting a plurality of vessels 27 through a defined path (the loop of the chain 213b). The transport device 213b conveys the reaction tubes to the wash station 214, pipette station 204, or returns the tube to the serpentine channel 213' for supplemental incubation (see for example col. 7, lines 43-50 and col.). In other words, Babson teaches the transport device transporting vessels from a wash station 214 to a defined path and from the defined path back into the wash station and then into a read station. The open “comprising” language of the claims do not preclude the transport device transferring the plurality of vessels from the defined path of the transport device 213b and into the read station 215a via the wash station 214. Also note that claimed *transport device 3 is defined in the specification and instant claim 10 as merely a continuous chain or belt* having vessel receptacles for receiving the vessels. The transport device 213b of Babson is a continuous chain or belt having vessel

receptacles for receiving a reaction vessel. Thus, transport device (continuous chain 3) as claimed does not include *any structure* that removes the vessels from the chain and places onto or out of the read station and wash station. In other words, the claimed transport device 3 contains no structure that distinguishes it from the chain 215a of Babson. Thus, for the reasons delineated above, the rejection of claims 1-4 and 10-17 should be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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